

### **CORRECTIONS TO THE DRAWINGS**

In response to the Examiner's objection to the drawings, a damper has been added to Figures 8A and 8B. The damper 102 is supported by the text describing Figures 8A, 8B, and 8C. No new matter has been added. A replacement drawing sheet including the corrected Figures 8a and 8B and showing Figures 8A, 8B, 8C, and 8D has been included in Appendix A. In view of the drawing corrections, the Applicants respectfully request withdrawal of the objections under 37 CFR 1.83(a).

### REMARKS

The September 13, 2006 Office Action was based on claims 1-31. This amendment cancels claims 23 and 31, amends claims 1, 8, 9, 11, 12, 13, 19, and 22, and adds new claims 32 and 33. Thus, after entry of this amendment, claims 1 through 22, 24 through 30, 32 and 33 are pending and presented for further consideration.

In the September 13, 2006 Office Action, the Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter in accordance with 37CFR 1.75(d)(1) and MPEP § 608.01(o). The Examiner also objected to the specification as failing to provide antecedent basis for the claimed major and minor axes of the projections claimed in claim 8.

The Examiner rejected Claims 1-31. The Examiner rejected Claims 19, 20, and 21 under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Examiner objected to the drawings under 37 CFR 1.121(d) as not showing the damper of Claim 7. The Examiner rejected Claims 1-18 and 24-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 was rejected because there was no antecedent basis for "the open jaw external frame distance" or "the projection of the jaws". Claim 9 was rejected because it was unclear how the spillage was substantially stopped, yet blood still flows through the wall of the vessel. Claims 11 and 13 were rejected because they contradict Claim 9 in the case where the wall of the vessel is the same as the lumen of the vessel. Claim 24 was rejected because there was no antecedent basis for "the padded tissue contacting surfaces of the jaws". Claims 25-28 were rejected because there was no antecedent basis for "said force parallelism". The Examiner objected to Claim 22 because of certain informalities, that is line 7 of Claim 22 "on" should be "one".

The Examiner rejected Claims 9 and 10 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2006/0190037 ("the Ginn et al. publication"). The Examiner rejected Claims 22 and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Number 4,932,955 ("the Merz et al. patent"). The Examiner rejected Claims 22 and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Number 3,805,792 ("the Cogley patent").

The Examiner rejected Claims 23 and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Number 4,932,955 ("the Merz et al. patent") or U.S. Patent Number 3,805,792 ("the Cogley patent") in view of U.S. Patent No. 6,802,848 ("the Anderson et al. patent"). In light of the following arguments, reconsideration of the pending claims, as amended, is respectfully requested.

**OBJECTION TO THE SPECIFICATION UNDER 37 CFR 1.75(d)(1) and MPEP § 608.01(o)**

The Examiner objected to the specification under 37 CFR 1.75(d)(1) and MPEP § 608.01(o) as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner alleges that the specification does not provide antecedent basis for a clip having jaws rotatably disposed about a (as in one) hinge, wherein the clip opens and closes with force parallelism and where the parallelism is maintained by a parallelogram hinge, or by a linear bearing. None of the disclosed embodiments have these maintaining means in conjunction with jaws rotatable about one hinge. The Examiner alleges that all the disclosed embodiments with these maintaining means have jaws, where each jaw is rotatable about a different hinge.

Support for a hinge providing force parallelism can be found on page 10, lines 3-13 and lines 29 through 31 and in Figures 1A, 1B, and 1C. In this part of the specification, the clip 10 utilizes a parallelogram hinge design to facilitate parallelism in the jaws 12 in the open, closed, and partially open configurations. The parallelogram hinge comprises a main hinge 18, a plurality of main struts 20, an optional secondary hinge 28, a plurality of optional secondary struts, a plurality of main pivot points 32, an optional hinge bracket 38, and a plurality of optional secondary pivot points 40. The Applicants respectfully submit that the parallelogram hinge is a single hinge entity, although it comprises a plurality of hinges, and applied it as such within the specification. Further support for the force parallelism can be found in Figures 10A and 10B along with the description in the specification (page 22, lines 7 through 33 and page 23, lines 1 through 7. In this embodiment, a single hinge 18 controls the jaws 12 but the pads 16 are of uneven thickness or hardness which provides approximately

even force distribution on the tissue but with less complexity than the other clip 10 embodiments. In view of this clarification, the Applicants respectfully request withdrawal of the objection to the specification under 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

#### **OBJECTION TO THE SPECIFICATION WITH REGARD TO CLAIM 8**

The Examiner objected to the specification as failing to provide antecedent basis for the claimed major and minor axes of the projections claimed in Claim 8. The Applicants submit that the major and minor axes are described in the specification corresponding to Figure 1C. Page 14, lines 5 through 18 state that the jaws 12 project along a major axis 19 generally leading perpendicularly away from the main hinge 18. The jaws 12 also project along a minor axis 21 leading generally parallel to the direction of the main hinge 18. The minor axis 21 should be no smaller than 25% of the major axis 19. In another embodiment, the major axis 19 should be no smaller than 25% of the minor axis 21. Claim 8 has been amended to more closely parallel the language of the specification. No change has been made to the specification. No new matter has been added. In view of this clarification, the Applicants respectfully request withdrawal of the objection to the specification with regard to proper antecedent basis for claim 8.

#### **REJECTION OF CLAIMS 19-21 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

The Examiner rejected Claims 19, 20, and 21 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the specification does not adequately describe how the tabs can be folded inwardly against the jaws. The Examiner alleges that, looking at Figure 12A, the tabs 80, 82 cannot be rotated to fold against the jaws while not also rotating the jaws to which they are obviously rigidly connected?

In response, the Applicants assert that the tabs 80 and 82 are not rigidly connected to the jaws. In the specification, page 24, lines 17 through 34 state that the jaws 12 rotate around the hinge mechanism 18 and are constrained radially by the hinge mechanism 18. The upper folding tab 80 is radially constrained around the hinge

mechanism 18 and is free to fold inward until it is essentially flush with the frame 14. The upper folding tab 18 has a projection that engages with the jaw 12 in the region of the hinge mechanism 18 so that when the upper folding tab 80 is forced downward by manual pressure, the upper jaw 12 is forced to rotationally open around the hinge mechanism 18. The lower folding tab operates similarly with regard to the lower jaw such that the lower jaw opens when the lower folding tab is pushed upward.

Thus, although the tabs 80 and 82 can rotate about the same hinge mechanism 18 as the jaws 12, they are not rigidly connected to the jaws 12. The tabs 80 and 82 engage the jaws 12 only when they engage projections on the jaws 12 and can force the jaws 12 to open. In the other direction, the tabs 80 and 82 do not engage any projections on the jaws and can be folded relatively flush with the frame 14. In light of these arguments, Applicants request that the Examiner withdraw the rejection to Claims 19-21 under 35 U.S.C. § 112, first paragraph.

#### **REJECTION OF CLAIMS 1-18 and 24-28 UNDER 35 U.S.C. § 112**

##### **Claim 1**

The Examiner alleges that there is no antecedent basis in claim 1 for “the open jaw external frame distance”, or “the projection of the jaws”. Claim 1 has been amended to provide antecedent basis for “the projection of the non-jaw component” and the “exterior frame distance”. With this amendment, the Applicants respectfully request withdrawal of the rejection to Claim 1 under 35 U.S.C. § 112.

##### **Claim 9**

The Examiner requests clarification and correction, in claim 9, regarding how the spillage is substantially stopped, yet the blood still flows through the wall of the vessel. There is a perception that the wall of the vessel actually should be the lumen of the vessel. Claim 9 has been amended to clarify that the vessel is a visceral organ, rather than a blood vessel. By way of clarification, the walls of visceral organs have blood vessels (arteries and veins) running through them and the walls of the visceral organs can be advantageously closed with the clip to prevent contents spillage from the lumen

of the visceral organ with less force than is necessary to close off a blood vessel. With this claim amendment, the Applicants respectfully request withdrawal of the rejection to Claim 9 under 35 U.S.C. § 112.

#### **Claims 11, 12, and 13**

The Examiner indicated that claims 11 and 13 contradict claim 9 in a specific interpretation. The Applicants have amended claims 11, 12, and 13 to clearly identify the vessel being clipped as visceral organs and thus blood vessels would exist within the walls of said visceral organs. The clip can seal the visceral organs from leakage of contents while still permitting the flow of blood through the arteries within the wall of the visceral organ. With these claim amendments, the Applicants respectfully request withdrawal of the rejection to Claims 11, 12, and 13 under 35 U.S.C. § 112.

#### **Claim 24**

The Examiner indicated that there was no antecedent basis for the “padded tissue contacting surfaces of the jaws”. The Applicants have amended claim 22, from which claim 24 depends, to correct the antecedent basis. With this claim amendment, the Applicants respectfully request withdrawal of the rejection to Claim 24 under 35 U.S.C. § 112.

#### **Claims 25-28**

The Examiner indicated that there was no antecedent basis for “said force parallelism” in claims 25, 26, 27, and 28. The applicants have amended claim 22, from which claims 25-28 depend, to correct the antecedent basis for “said force parallelism”. With this claim amendment, the Applicants respectfully request withdrawal of the rejection to claims 25-28 under 35 U.S.C. § 112.

#### **Claim 22**

The Examiner objected to Claim 22 because of a typographical error. Applicants have amended claim 22 to correct the typographical error. With this claim amendment, the Applicants respectfully request withdrawal of the objection to claim 22.

**REJECTION OF CLAIMS 9 and 10 UNDER 35 U.S.C. § 102(e)**

The Examiner rejected Claims 9 and 10 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2006/0190037 ("the Ginn et al. publication"). In view of the following discussion, Applicant respectfully traverses this rejection.

**Claim 9**

Ginn et al. appear to disclose a vascular puncture closure apparatus and methods. The method of Ginn et al. appears to close the wall of a blood vessel to prevent leakage while maintaining flow within the lumen of the blood vessel. The Ginn et al. publication does not appear to teach or disclose closing the wall of a visceral organ such that blood flow in the vasculature within the wall of the visceral organ is maintained.

In contrast, in an embodiment of the invention, a method is provided for achieving wound closure in a visceral organ of the body comprising the steps of accessing the site of the wounded visceral organ, applying one or more clips to the tissue surrounding the wound so that spillage of the visceral organ contents is substantially stopped but blood flowing through the wall of said wounded visceral organ is not stopped, and then removing the clips from said wounded tissue at a later time.

Because the Ginn et al. reference does not disclose, teach or suggest the closure of visceral organs with vascularized walls, the Applicants assert that Claim 9 is not anticipated by Ginn et al. Applicants, therefore, respectfully submit that Claim 9 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 9.

**Claim 10**

Claim 10, which depends from Claim 9, is believed to be patentable for the same reasons articulated above with respect to Claim 9, and because of the additional features recited therein.

**REJECTION OF CLAIMS 22 and 24 UNDER 35 U.S.C. § 102(b)**

The Examiner rejected Claims 22 and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,932,955 ("the Merz et al. patent"). In view of the following discussion, Applicants respectfully traverse this rejection.

**Claim 22**

Merz et al. appear to disclose a clip and clip applier for use with a blood vessel. The Merz et al. patent appears to disclose relatively narrow, serrated jaws that are appropriate to completely close off an artery such as the aorta but would cause damage to viscera by tissue trauma or by shutting off the blood supply within the wall of the viscera. The clip applier disclosed by Merz et al. appears to be a standard clip applier.

In contrast, in an embodiment of the invention, a system is disclosed for closing a wound in viscera having a lumen comprising a surgical clip comprising opposing jaws rotatably disposed about a hinge, wherein the jaws comprise large, padded tissue contacting surfaces having a generally hollow circular configuration, and further wherein the jaws substantially exert force parallelism when they contact a tissue, a spring operably engaging the jaws to bias the jaws shut, at least one opening tab secured to each jaw, wherein the opening tabs are disposed between the hinge and the distal extent of the jaw such that they do not extend proximally from the hinge; said opening tabs being operable to open and close the jaws, and a grasping instrument comprising a pair of jaws adapted to engage the opening tabs and apply force to the opening tabs to open the surgical clip, said jaws having a hinge accommodating space adapted to receive the hinge, and bosses located on the jaws so as to engage the opening tabs when the hinge is disposed within the hinge accommodating space, wherein the spring force of the spring is limited so that the force applied by the clip to the viscera to prevent closure of blood vessels within the wall of the viscera while causing complete closure of the wall of the viscera being clipped against the loss of visceral contents.

Because the Merz et al. reference does not disclose, teach or suggest the closure of visceral organs with vascularized walls while permitting the flow of blood within the visceral organ walls, or padded jaws having a generally large footprint, the



Applicants assert that Claim 22 is not anticipated by Merz et al. Applicants, therefore, respectfully submit that Claim 22 is patentably distinguished over the cited references and applicants respectfully request allowance of Claim 22.

#### **Claim 24**

Claim 24, which depends from Claim 22, is believed to be patentable for the same reasons articulated above with respect to Claim 22, and because of the additional features recited therein.

#### **REJECTION OF CLAIMS 22 and 24 UNDER 35 U.S.C. § 102(b)**

The Examiner rejected Claims 22 and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,805,792 ("the Cogley patent"). In view of the following discussion, Applicants respectfully traverse this rejection.

#### **Claim 22**

Cogley appears to disclose a clip and clip applier for use with a blood vessel. The Cogley patent appears to disclose relatively narrow jaws that are appropriate to completely close off an artery but would cause damage to viscera by tissue trauma or by shutting off the blood supply within the wall of the viscera. The clip applier disclosed by Cogley appears to be a standard clip applier.

In contrast, in an embodiment of the invention, a system is disclosed for closing a wound in viscera having a lumen comprising a surgical clip comprising opposing jaws rotatably disposed about a hinge, wherein the jaws comprise large, padded tissue contacting surfaces having a generally hollow circular configuration, and further wherein the jaws substantially exert force parallelism when they contact a tissue, a spring operably engaging the jaws to bias the jaws shut, at least one opening tab secured to each jaw, wherein the opening tabs are disposed between the hinge and the distal extent of the jaw such that they do not extend proximally from the hinge; said opening tabs being operable to open and close the jaws, and a grasping instrument comprising a pair of jaws adapted to engage the opening tabs and apply force to the opening tabs to

open the surgical clip, said jaws having a hinge accommodating space adapted to receive the hinge, and bosses located on the jaws so as to engage the opening tabs when the hinge is disposed within the hinge accommodating space, wherein the spring force of the spring is limited so that the force applied by the clip to the viscera to prevent closure of blood vessels within the wall of the viscera while causing complete closure of the wall of the viscera being clipped against the loss of visceral contents.

Because the Cogley reference cited by the Examiner does not disclose, teach or suggest the closure of visceral organs with vascularized walls while permitting the flow of blood within the visceral organ walls, or padded jaws having a generally large, hollow footprint, the Applicants assert that claim 22 is not anticipated by Cogley. Applicants, therefore, respectfully submit that claim 22 is patentably distinguished over the cited references and applicants respectfully request allowance of claim 22.

#### **Claim 24**

Claim 24, which depends from claim 22, is believed to be patentable for the same reasons articulated above with respect to claim 22, and because of the additional features recited therein.

#### **REJECTION OF CLAIMS 23 and 29-31 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 23 and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over the Merz or Cogley patents in view of U.S. Patent No. 6,802,848 ("the Anderson et al. patent").

#### **Claims 23 and 29-31**

Claim 23 has been canceled and its features incorporated into Claim 22.

Claim 31 has been canceled since it was redundant to claim 21.

With regard to claim 22, Anderson et al. '848 appears to disclose a surgical clip, to occlude body conduits such as blood vessels, having narrow parallel jaws and a bias spring with user adjustable compression and a lock to continuously secure the position of the jaws along the longitudinal axis of the spring.

Anderson et al. do not appear to teach or disclose jaws with a large ring-shaped footprint, or the use of the clip to occlude viscera where the walls of the viscera are vascularized. A blood vessel clip such as the one of Anderson et al. would appear to cause ischemia and necrosis of the visceral wall. The narrow jaw design of Anderson et al. does not appear to be capable of sealing a wound in the visceral wall.

In contrast, in an embodiment of the invention, a system is disclosed for closing a wound in viscera having a lumen comprising a surgical clip comprising opposing jaws rotatably disposed about a hinge, wherein the jaws comprise large, padded tissue contacting surfaces having a generally hollow circular configuration, and further wherein the jaws substantially exert force parallelism when they contact a tissue, a spring operably engaging the jaws to bias the jaws shut, at least one opening tab secured to each jaw, wherein the opening tabs are disposed between the hinge and the distal extent of the jaw such that they do not extend proximally from the hinge; said opening tabs being operable to open and close the jaws, and a grasping instrument comprising a pair of jaws adapted to engage the opening tabs and apply force to the opening tabs to open the surgical clip, said jaws having a hinge accommodating space adapted to receive the hinge, and bosses located on the jaws so as to engage the opening tabs when the hinge is disposed within the hinge accommodating space, wherein the spring force of the spring is limited and pre-set so that the force applied by the clip to the viscera to prevent closure of blood vessels within the wall of the viscera while causing complete closure of the wall of the viscera being clipped against the loss of visceral contents.

There is no motivation by Anderson et al. to apply a controlled pressure, which is specifically pre-set, to permit blood flow but prevent spillage of visceral contents and leaves the amount of force adjustment up to the user. There is no motivation to combine Anderson et al. with Merz or Cogley to clip a visceral organ and none of these references anticipate the issues involved with clipping hollow viscera. Applicants, therefore, respectfully submit that Claim 22 is patentably distinguished over the cited references and applicants respectfully request allowance of Claim 22.

Claims 29-30, which depend from claim 22, are believed to be patentable for the same reasons articulated above with respect to claim 22 and because of the additional features recited therein.

Claim 21 and canceled claim 31, which depend from claim 19, are believed to be patentable for the same reasons articulated above with respect to Claim 19 and because of the additional features recited therein. Neither Anderson, Cogley, nor Merz disclose or teach grasping tabs that can be folded out of the way after they are used to open the jaws. Applicants, therefore, respectfully submit that Claim 19 is patentably distinguished over the cited references and applicants respectfully request allowance of Claim 21.

#### **AUTHORIZATION OF ASSIGNEE**

Jay A. Lenker, CEO, an officer of Damage Control Technologies, Inc, which is the assignee of U.S. Patent Application No. 10/663,038 authorizes an inventor, Jay A. Lenker, to respond to the outstanding Office Action.

#### **CONCLUSION**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

Dated: 13 December 2006

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**Appendix A**  
**Corrected Drawings**